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PATENT

Practitioner's Docket No. 2260/119

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Grahek, et al.
Application No.: 10/698,009 Group No.: 1626
Filed: October 30, 2003 Examiner: Shameem, G.
For: Process for Obtaining HMG-CoA Reductase Inhibitors of High Purity

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
BEFORE MAILING DATE OF EITHER A FINAL ACTION
OR NOTICE OF ALLOWANCE (37 C.F.R. § 1.97(c))

TIME OF TRANSMITTAL OF ACCOMPANYING
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either
- (1) a final action under § 1.113 or
 - (2) a notice of allowance under § 1.311

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*
(When using Express Mail, the Express Mail label number is *mandatory*;
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. § 1.8(a)

☒ with sufficient postage as first class mail.

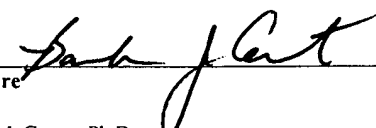
37 C.F.R. § 1.10*

☐ as "Express Mail Post Office to Addressee"
Mailing Label No. _____ (mandatory)

TRANSMISSION

☐ facsimile transmitted to the Patent and Trademark Office, (703) _____

Date: March 7, 2006

Signature: 
Barbara J. Carter, Ph.D.
(type or print name of person certifying)

* Only the date of filing (' 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under ' 1.8 continues to be taken into account in determining timeliness. See ' 1.703(f). Consider "Express Mail Post Office to Addressee" (' 1.10) or facsimile transmission (' 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

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whichever occurs first.

CHOOSE ONE:

STATEMENT

2. Accompanying this transmittal is a statement as specified in 37 C.F.R. section 1.97(e).

OR

FEE

2. Accompanying this transmittal is the fee for submission of an information disclosure statement under section 1.97(c). (\$180.00)

FEE PAYMENT

3. Applicant elects the option to pay the fee set forth in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under § 1.97(c) (\$180.00).

Fee due \$180.00

METHOD OF PAYMENT OF FEE


4. Attached is a check in the amount of \$180.00

Charge any additional fees required by this paper or credit any overpayment to Deposit Account No. 19-4972.

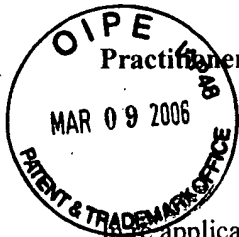
A duplicate of this paper is attached.

DATE:

March 7, 2006


Barbara J. Carter, Ph.D.
BROMBERG & SUNSTEIN LLP
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125 Summer Street
Boston, MA 02110-1618
US

02260/00119 472101.1



Practitioner's Docket No.

2260/119

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Grahek, et al.

Application No.: 10/698,009

Group No.: 1626

Filed: October 30, 2003

Examiner: Shameem, G.

For: Process for Obtaining HMG-CoA Reductase Inhibitors of High Purity

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

(Information Disclosure Statement--page 1 of 6)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is **mandatory**;

Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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[X] deposited with the United States Postal Service in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10*

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TRANSMISSION

[] transmitted by facsimile to the Patent and Trademark Office.

Date:

March 7, 2006

Signature

Barbara J. Carter, Ph.D.

(type or print name of person certifying)

*WARNING:

Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Supplemental Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

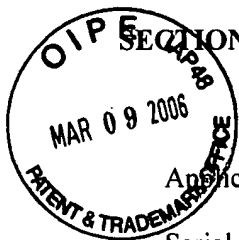
NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.



SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Grahek, et al. Attorney Docket: 1626
Serial No: 10/698,009 Art Group Unit: 1626
Date Filed: October 30, 2003 Examiner Name: Shameem, G.
Invention: Process for Obtaining HMG-CoA Reductase Inhibitors of High Purity

LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AS	US 6,689,590 B2	Feb. 10, 2004	Keri, et al.	435/135
	AT	US 6,936,731 B2	Aug. 30, 2005	Keri, et al.	560/256

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	AU	Arai, et al.	<i>Pravastatin Sodium (CS-514), A Novel Cholesterol Lowering Agent Which Inhibits HMG-CoA Reductase</i> , Annu. Rep. Sankyo Res. Lab., 40; 1-38, 1988

Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☒ Exception(s) to above:

U.S. patent citations are not included pursuant to the United State Patent and Trademarks Office's September 21, 2004 waiver of the copy requirement in 37 CFR 1.98 for cited pending U.S. patent citations when the patent citations are available in the USPTO's IFW system.

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this certification is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

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02260/00119 472090.1



SIGNATURE OF PRACTITIONER

Barbara J. Carter, Ph.D.

(type or print name of practitioner)

125 Summer Street, 11th Floor

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Boston, MA 02110-1618